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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,200	01/30/2004	Moon K. Song	MOONSO.003A	6051

20995 7590 01/27/2006

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/768,200

Applicant(s)

SONG, MOON K.

Examiner

Christopher R. Tate

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/03/04, 08/30/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-23 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 14 (and throughout many of the claims that depend therefrom) the phrase "wherein said pharmaceutical composition comprises: ... mg/kg/day" of the recited ingredients. However, this phrasing is unclear and confusing because an ingredient (such as the instantly recited "zinc cation", "cyclo-Hispro", "arachidonic acid", and "histidine") within such a composition cannot properly be defined by the instantly claimed measurement of "mg/kg/day". This type of measurement would only be applicable to defining a method in which an ingredient within a composition is at a concentration so as to provide a level of the ingredient with respect to the mg amount provided per kg (body weight) per day, but is not applicable to a direct level of such ingredients within a composition. Please note that the instant specification discloses this concept (see, e.g., paragraphs [0010]-[0012] and [0030]-[0036]) - i.e., the actual amount ranges of each of the recited ingredients are disclosed which correspond to providing a mg/kg/day amount thereof. For example, the instant specification teaches that "the amount of zinc cation can range from about 1 to about 100 mg, preferably about 5 to about 50 mg" [within such a

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composition] ... For an average human weighing 70 kilograms this is equivalent to the amount of zinc cation ranging from about 0.01 to about 1.4 mg/kg/day, preferably about 0.07 to about 0.7 mg/kg/day, and more preferably about 0.1 to about 0.4 mg/kg/day" (see, e.g., paragraph [0010]. Thus, the actual amount range of zinc cation within the instantly claimed administered composition would appear to actually be, e.g., within the ranges of about 1 to about 100 mg, and preferably about 5 to about 50 mg (so as to correspondingly provide an *in vivo* concentration of zinc cation within a 70 kg human subject equivalent to about 0.01 to about 1.4 mg/kg/day, preferably about 0.07 to about 0.7 mg/kg/day, and more preferably about 0.1 to about 0.4 mg/kg/day therein). This holds true for all of the recited ingredients instantly claimed.

Claims 10 and 21 are rendered vague and indefinite by the phrase "said treatment is also for hypertension and/or high cholesterol". It is unclear by this non-positively claimed phrase if the treated subject is actually also suffering from such conditions (in addition to being overweight/obese), if this is attempting to define a prophylactic treatment (e.g., to help prevent an overweight/obese subject from developing hypertension and/or high cholesterol), or something else.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hwang et al. (Diabetes, Obesity and Metabolism, March 2002) in view of Song (US 5,834,032).

A method of treating an overweight or obese mammal via administering a pharmaceutical composition comprising mg/kg/day amount ranges (see USC 112, second paragraph above with respect to the unclarity of "mg/kg/day" within such a composition) of zinc (in the form of a zinc cation and anion - such as a zinc salt) and arachidonic acid or cyclo-Hispro is apparently claimed.

Hwang et al. beneficially teach treating obese diabetic mice with a pharmaceutical composition comprising zinc and arachidonic acid (see entire document including Abstract and Discussion). Hwang et al. do not expressly teach employing a zinc salt, nor cyclo-Hispro for such treatment.

Song beneficially teaches treating diabetic mice (so as to improve and/or alleviate various diabetic ailments) via administering pharmaceutical compositions comprising zinc salts (including zinc cations within the actual instantly disclosed effective mg ranges corresponding the instantly claimed mg/kg/day ranges), arachidonic acid (within the actual instantly disclosed effective mg ranges corresponding the instantly claimed mg/kg/day ranges), and/or cyclo-Hispro (within the actual instantly disclosed effective mg ranges), as well as histidine (within the actual instantly disclosed effective mg ranges corresponding the instantly claimed mg/kg/day ranges). Song also beneficially teaches that such pharmaceutical compositions can be given two to four times daily as well as within a dietary supplement (see, e.g., col 1, line 13 - col 5, line 63; col 15, lines 8-34; and claims).

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat a diabetic subject, including an obese diabetic subject, by administering a pharmaceutical composition comprising result-effective amounts of zinc (in the form of a zinc salt having zinc cations and anions), arachidonic acid, cyclo-Hispro, and histidine based upon the beneficial teachings provided by the cited references, as discussed above. In addition, please note that it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose (to treat diabetes within a subject suffering therefrom including an obese diabetic subject; as well as to use the combination for such purpose - within a method of treatment) in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). If not expressly taught by the cited references, the adjustment of particular conventional working conditions (e.g., determining a result-effective amount of one or more of the instantly claimed ingredients to use in treating an obese diabetic subject) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, having the references before him/her as a guide. Further, with respect to the product-by-process claims concerning the cyclo-Hispro (within the administered composition) being obtained from soybeans via the recited process steps (see, e.g., instant claims 11-13), please note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious

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from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process.” In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product (within the administered composition) and the prior art product (within such an administered composition). In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). See MPEP 2113.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
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